ABSTRACT

Methods and articles of manufacture are disclosed for detecting a secreted mycobacterial antigen directly in a biological sample obtained from a mammalian subject without substantial replication of mycobacterial cells in the sample. This method comprises contacting an antibody that specifically binds to the secreted mycobacterial antigen with the sample, or a fraction thereof, under conditions such that the antibody specifically binds to secreted mycobacterial antigen in the sample, thereby forming a specific complex of the antibody with the secreted mycobacterial antigen. This method further comprises detecting the presence, absence or amount of specific complex of the antibody with the secreted mycobacterial antigen in the sample. In this method the presence of this specific complex indicates the presence of the secreted mycobacterial antigen in the sample. The invention method is particularly useful for detecting MPB64 antigen of *M. bovis* or MPT64 antigen of *M. tuberculosis* in biological samples from a human subject suspected of having tuberculosis, particularly for sputum samples from such subjects. Prior to contacting the sample with an antibody that specifically binds to MPB64 antigen or MPT64 antigen, a mucolytic or liquifying agent, preferably containing a disulfide bond reducing agent, and optionally a decontaminating agent, is added to the sample. One preferred disulfide bond reducing agent is N-acetyl-L-cysteine (NALC) and advantageously this agent is added to the sample to achieve a concentration in the sample that is substantially greater than 0.25% (w/v), for instance, about 2.5% (w/v).